K062342
p1/4

Section 6 – 510(k) SUMMARY

510(k) Summary As Required by 21 CFR 807.92 (c)

SEP 25 2006

Owner: Sentra Medical Devices LLC
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Canton, MI 48188

Contact Person: Karthik Narayan

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Date of Summary: 04-30-2006

Device Information

Trade Name	True Pulse Invasive Blood Pressure Monitoring Kit
Common Name	Invasive Blood Pressure Monitoring Kits
Classification Name	Transducer, Blood -pressure, Extravascular
C F R Section	870.2850
Product Code	DRS

Predicate Device

Edwards Lifesciences Pressure Monitoring Kit with TruWave Disposable Pressure Transducer has been chosen as the predicate device for this pre -market application.
The filing of the 510(k) associated with this pre dicate device is K832907, filed by American Pharmaseal, a Baxter Edwards company, for a blood pressure transducer including a continuous flush device, marketed by Edwards Life sciences .

Description of the Device

Sentra's 'TruePulse' Invasive Pressure Mon itoring Kits are indicated for use in physiological, invasive pressure measurement, and are for use with patients requir ing intravascular pressure monitoring.

The True Pulse Disposable Blood Pressure Kit from Sentra medical d evices LLC consists of a Arterial extension line (available in various standard lengths) is attached via a luer connection to the catheter that is inserted into the patient, (the male portion of the lumen is a part of the kit and the female portion of the lumen is a part of the catheter, the catheter is not a part of this device) a stopcock, a monitoring line, to another stopcock, a transducer, a continuous flow flush device, and an IV set all connected by standard luer connections.

The device functions by continuously monitoring changes in blood pressure from the function of the heart. The pressure waves generated in the heart are transmitted through the vascular system, to the catheter and then through the saline fluid - filled tubing to a transducer. Up on reaching the transducer, pressure waves from the fluid pathway depress a diaphragm, changing the resistance to the flow of current through a circuit. The change in resistance produces an electrical event that creates a signal that is then transmitted t o a monitor through a cable and displaying pressure reading and a wave form on a monitor. (The catheter and monitor are not parts of this kit).

Intended Use

Usually patients who require this type of monitoring have one of two major common factors, failure of the heart to pump effectively or a major disturbance of the circulatory system. The heart failure can be the result of several diseases such as acute myocardial infarction, long-standing valve disease, and cardio-myopathy. Major disturbances of the circulatory system may be major blood loss due to trauma, major surgery, or excessive fluid shifts within the body.

Comparison of the True Pulse Disposable Blood Pressure Kit to the predicate device.

The True Pulse Disposable Blood Pressure Kit is being compared to the Edwards Life sciences Pressure Monitoring Kit with TruWave Disposable Pressure Transducer (Ref: PX260). Components of each kit are described in the table below.

Usage comparison

Item	Sentra's True Pulse	Edwards TruWave	Comments
Basic description	Single use transducer kit	Single use transducer kit	Similar
Target usage	Patients requiring invasive pressure measurement and monitoring	Patients requiring invasive pressure measurement and monitoring	Similar usage
Where used	In Hospitals, by trained health care personnel	In Hospitals, by trained health care personnel	Similar
Sterilization	ETO sterile	ETO sterile	Similar type of sterilization
Packaging	Coiled and taped tubes in a Tyvek and Mylar pack, heat sealed peel-open package	Coiled and taped tubes in a Tyvek and Mylar pack, heat sealed peel-open package	Similar type of packaging

Technological Characteristics comparison

Kit Components	Sentra's True Pulse	Edwards TruWave	Comments
Arterial Extension Line	Extruded PVC tube bonded to Luers at both ends	Extruded PVC tube bonded to Luers at both ends	Similar design & construction, similar functions
Stopcock for fluids collection	Molded housing with handle rotating a core, Luer ends, cap	Molded housing with handle rotating a core, Luer ends, cap	Similar design & construction, similar functions
Monitoring Line	Extruded PVC tube bonded to Luers at both ends	Extruded PVC tube bonded to Luers at both ends	Similar design & construction, similar functions
Stopcock for zeroing	Molded housing with handle rotating a core, one Luer end, non-vented cap	Molded housing with handle rotating a core, Luer ends, vented cap	Similar design & construction, similar functions
Pressure Transducer. (Industry consensus Standard met)	Meets **AAMI: BP22 1995, R2001**. Which combines **AAMI BP22 1986** *Blood pressure transducers* and **AAMI BP23:**	Meets **AAMI BP23:** 1986.*Intercangeability and performance of resistive bridge type blood pressure transducers. (Per IFU)*	Minor differences in over all construction, similar functions. Transducer used in Sentra kit meets or exceeds the

	1986.*Intercangeability and performance of resistive bridge type blood pressure transducers.* Stand alone transducer, injection molded housing, Pole or patient arm mounted, wheat Stone bridge connector, sensor element isolated by gel, Luer ends.	Stand alone transducer, injection molded housing, Pole or patient arm mounted, wheat Stone bridge connector, sensor element isolated by gel, Luer ends.	standards that Edwards transducer meets, as outlined in the comparison column.
Flush Device	Injection molded housing, Squeeze handle changes flow rate, Luer connections, stand alone flush device	Injection molded housing, pulling tab changes flow rate, integrated in transducer housing	Differences in over all construction, similar function
IV Set	Molded spike, drip chamber, tube bonded to Luer, roller clamps	Molded spike, drip chamber, tube bonded to Luer, roller clamp	Similar construction, function

Edwards TruWave transducer housing has integrated in it, a stop-cock and flush device while in Sentra's design these items are stand-alone. The reason for integration in Edwards design is cost savings and the two kits were found to be substantially equivalent in function.
The two kits were found to be substantially equivalent based on the following functional tests performed on 4 samples each of the two devices.

- Luer inspection *per ISO 594*
- De-bubbling and leak
- Output flow
- Transducer Zero setting
- Square wave response
- Prolonged exposure dwell with 300 mmHg saline pressure, and pressure accuracy during and after prolonged exposure
- Volume of kit CC

This bench testing of the Sentra Kits as compared to the Edward's Kits showed that the Sentra Kit served the same functions with the same degree of safety as the Edward's Kits.

Design

Specifications for components and packaging including materials used, functions required were developed. Kits were built and sterilized with production intent methods and processes. These kits were then used for functional and predicate device comparison testing.

Sentra has utilized Failure Modes and Effects Analysis to estimate and mitigate risks.

Materials for the kits components were chosen with careful analysis of material properties. Detailed material properties, and the list of materials used are discussed in the Sentra's 510(k) sections and exhibits.

Drawings of the components, assembly have been provided in the 510(k).

Sentra will market standard variants of the base design. The variation is only in the presence or absence of some of the components, variations in lengths of the tubes, while utilizing the same materials and base design verified in testing. A matrix showing these variants is discussed in the 510(k).

Testing and verification

The Sentra Kit has passed sterilization tests, bio-compatibility requirements, and product performance standards set forth by Sentra as proven in bench tests. International standards have been adopted in several areas, deemed important. The tests conducted, flow, procedures, acceptance criteria and results are discussed elsewhere in the 510(k).

All tests were designed in a test flow, with detailed test procedures and tests were executed in 2 legs, one was for functional verification of the kits and second for proof of substantial equivalence.

The transducer complies with the industry consensus standard AAMI BP22: 1995 R 2001 tested by our transducer supplier. Results are provided in the 510(k) Exhibit 1.

Detailed discussion and results on all of these topics are available in Sentra's 510(k) sections and exhibits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2006

Sentra Medical Devices, LLC
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K062342
Trade Name: Sentra True Pulse Invasive Pressure Monitoring Kit
Regulation Number: 21 CFR 870.2850
Regulation Name:Extravascular Blood Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DRS
Dated: September 9, 2006
Received: September 11, 2006

Dear Mr. Job:

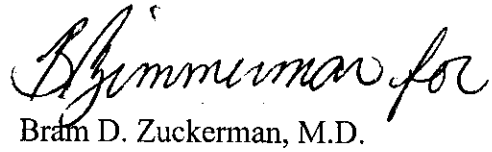
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062342

Section- 5

Indications for Use

510(k) Number (if known): Not issued yet.

Device Name: Sentra True Pulse Invasive Pressure Monitoring Kit

Indications For Use:

Sentra's 'TruePulse' Invasive Pressure Monitoring Kits are indicated for use in physiological, invasive pressure measurement, and are for use with patients requiring intravascular pressure monitoring.

Prescription Use : Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062342